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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,154	07/13/2006	Ian Robert Baldwin	PB60663	6853

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EXAMINER
CHANG, CELIA C

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
10/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/597,154	BALDWIN ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of group I, claim 14 and claims 1-11, 13, 15-22 reading on Z1 is piperidine in the reply filed on Jun 22, 2009 is acknowledged. The traversal is on the ground that the groups are merely different embodiments of a single inventive concept. This is not found persuasive because it was clearly delineated in the restriction that different "core" are recognized by the field to have different utility. The evidence provided in the previous office action indicated that the Markush grouping is improper but should be independent invention. In addition, it was also delineated that separate and diverse classes and subclasses which are not co-extensive with each other must be searched if restriction is not made, which is a tremendous burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 26-38 have been canceled. Claim 14, and claims 1-11, 13, 15-22 with example 45 as the elected species is prosecuted. Claims 23-25 and the remaining subject matter of claims 1-11, 13, 15-22 are withdrawn from consideration per 37 CFR 1.142(b).

2. Claims 20-22 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The term "for use in treatment of a disorder mediated by inappropriate IKK2 activity" is not limiting since a compound cannot be separated from its activity. Thus, the scope of claim 22 is the same as claim 1. Cancellation of one claim is recommended.

3. Claims 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of the claims are ambiguous because it is unclear what constitutes "inappropriate kinase activity" or what is mediated by inappropriate IKK activity. Please note

that the term inappropriate and mediate includes both hyper- and hypo-activity of such mechanism. While a single compound can affect the physiological mechanism by enhancing or inhibiting its ultimate physiological functionality, it has not been known that a single compound can be active in both enhancing and inhibiting simultaneously. The scope of the claims are thus confusing.

4. Claims 1, 18-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims encompassed the scope of "solvates of the compounds" for which no description or enabling support can be found in the specification. Please note that each solvate is a different "chemical identity" and there should never be any doubt in this century as to the chemical identity of a material (see Suddon). Unlike formation of salts between a pharmaceutically acceptable acid and an organic base compound of the claims, the formation of "solvates" must find descriptive and enabling support for such claimed scope because absent of specific description, one having ordinary skill in possession of compounds would not be able to offer any predictability of which one will form what solvate (see Braga p.3640). A survey of the specification indicated there is no description of which solvent can form solvate with the compounds, under what condition will such solvates be obtained, and whether the solvates will have consistent properties to be considered inclusive as being a "Markush" alternative of the compounds.

No examples, no process of making, no starting material or operability can be found for any compound encompassed by the Markush formula to have the ability in forming what solvate. Therefore, absent of description and enabling disclosure, the specification is insufficient in supporting the "claimed" scope of "solvates of the compounds".

The claims encompassed the scope of "physiologically functional derivative" of the compounds, for which no description or enabling support can be found in the specification. Please note that a derivative is not the claimed compound but a modification of the claimed compound. A survey of the specification indicated there is not description of what constitutes

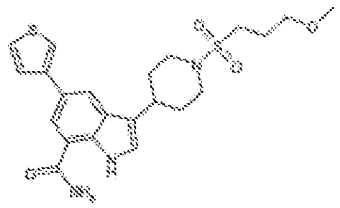
"physioilogically functional derivatives". Absent of what is the chemical structure of such modification and how to modify which structure to the modified structure, the specification provided mere language rather then enablement of a chemical material with clear identity.

5. Claims 1-11, 13-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable the copending claims of SN 11/931,189 or SN 11/575,416 in view of Patani et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because overlapping subject matter are embraced in all pending cases with specific anticipatory species rendered the genus prima facie obvious.

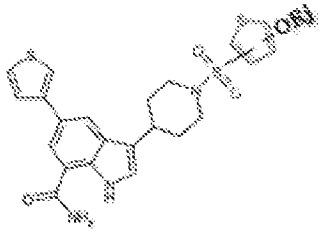
(A)

Determination of the scope and content of the prior art (MPEP §2141.01)

The species of SN 11/575,416, p.11 last compound of claim 56 has the structure as:



based on the generic claim 1 when V is piperidin-4-yl substituted with SOmR4, the R4 is XR5, X is alkyl, R5 is ORj, and Rj is alkyl. The generic equivalency claimed for XR5 is X can be heteroaryl (thienyl), thus the equivalency encompassed by the claims is:



Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the copending claims as delineated by the structure supra is that the moiety corresponding to the R6 of SO2R6 in Z1 is that the instant claims have a phenyl while the '416 is thienyl.

Finding of prima facie obviousness---rational and motivation (MPEP§2142-2143)

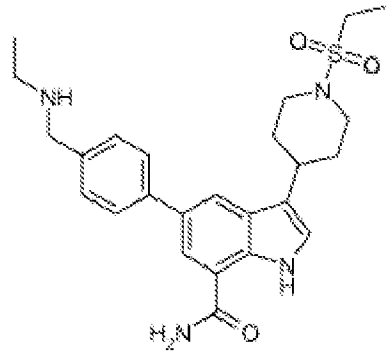
The replacement of a phenyl moiety with a thienyl moiety is the classic bioisosteric replacement based on size and structure similarity (Patani et al. p.3158, section E). One having ordinary skill in the art in possession of the instantly claimed phenyl moiety is tantamount to in

possession of the thiophene replaced compound because it was clearly recognized in the art that bioisosteric replacement is a design choice in medicinal chemistry.

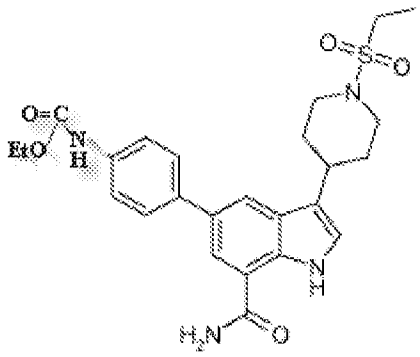
(B)

Determination of the scope and content of the prior art (MPEP §2141.01)

The species of claim 21, 1st compound on p.21 is:



which is generically when R1 is XYZ, X is phenyl, Y is C1, Z is NR4R5, R4 is H, R5 is alkyl. Therefore generically, the claims encompassed the compound as:



when X is phenyl, Y is bond, Z is NR4R5, R4 is H, R5 is COOEt.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the copending claims as delineated by the structure supra is that the R1 of the instant claims including the elected species is that the instant claims are phenyl optionally amide (NHCOR3) substituted or unsubstituted while the corresponding moiety is ester substituted.

Finding of prima facie obviousness---rational and motivation (MPEP§2142-2143)

The interchangeability between an amide bond linkage with an ester linkage has been well recognized in the art being a bioisosteric replacement based on size and structure similarity (Patani p.3170, table 48). One having ordinary skill in the art in possession of the instantly claimed amide moiety is tantamount to in possession of the ester replaced compound because it was clearly recognized in the art that bioisosteric replacement is a design choice in medicinal chemistry.

In addition, the independently claimed species of claim 33 on p.377 is a one methylend inserted compound of the instant claims i.e. the substituent on R1 is hydroxylmethyl instead of

hydroxyl. One methylene insertion of a compound is ordinarily considered prima facie structural obvious since such structural modification is considered within the sphere of obviousness around the ring substitutents. In re Ruddy, 121 USPQ 427; Ex parte Gresham 121 USPQ 422.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Oct. 21, 2009

/Celia Chang/
Primary Examiner
Art Unit 1625